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Please find below a communication from the EXAMINER in charge of this application.

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 26

Serial Number: 08/012,269
Filing Date: February 1, 1993
Appellant(s): Kwon

Christopher A. Michaels
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed June 17, 1996.

(1) *Status of claims.*

The statement of the status of claims contained in the brief is correct.

(2) *Status of Amendments After Final.*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(3) *Summary of invention.*

The summary of invention contained in the brief is correct.

(4) *Issues.*

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: The rejection of claims 1-3 and 22 under 35 U.S.C. § 101 and § 112, first paragraph are withdrawn upon reconsideration, because the instant specification does adequately teach how to use the instant claimed cDNA to make an antibody which is used to stimulate T cell proliferation.

(5) *Grouping of claims.*

The brief includes a statement that the claims stand or fall together.

(6) *Claims appealed.*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(7) *Prior Art of record.*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

Kwon, B.S. et al. 1989. "cDNA sequences of two inducible T-cell genes". Proceedings of the National Academy of Sciences USA, vol. 86, p. 1963-1967.

(8) *New prior art.*

No new prior art has been applied in this examiner's answer.

(9) *Grounds of rejection.*

The following ground(s) of rejection are applicable to the appealed claims.

Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 is drawn to a Markush group of chemical compounds, consisting of a) DNAs which encode a specific amino acid sequence, and b) DNAs "that can be used a hybridization probes to isolate a sequence of subparagraph a)". It is not clear which compounds are claimed in subparagraph b), since it is not clear what DNAs are sufficiently specific to be used as probes to isolate a sequence of subparagraph a). To meet the claim limitations, is it sufficient that the DNA cross-hybridize under low stringency, or is it necessary that the DNA be able to hybridize only to a molecule of subparagraph a) in a mixture containing complete mouse genomic DNA? Furthermore, it is not clear what compounds meet the claim limitations, since it is not clear what regions of the sequence are

required for the recited use as probes. It is also not clear whether the DNA of part b) consists of or comprises nucleotides that can be used as hybridization probes. For these reasons, the claim is seen as indefinite.

Claims 1-3 and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kwon et al. In making this rejection, appellant is denied the benefit of parent application 07/267,577, because the '577 application does not meet the requirements of 35 USC § 101 or §112, first paragraph. Kwon et al teaches the 4-1BB cDNA, and was published more than 1 year prior to the effective filing date of the claimed invention, thereby anticipating the claimed invention.

(10) *New ground of rejection.*

This Examiner's Answer does not contain any new ground of rejection.

(11) *Response to argument.*

In regard to the rejection of claim 22 as indefinite, appellant argues that the specification teaches examples of probes encompassed by the claim, and argues that one skilled in the art would known how to select probes from a known sequence. However, this argument deals with issues of enablement, and the issue is not the ability of one skilled in the art to make probes. The issue is one of defining the metes and bounds of the claimed subject matter. Part (b) of claim 22 is not limited to probes selected from a known sequence, but is drawn to "nucleotides that can be used as

hybridization probes to isolate a sequence of subparagraph a)." Since it is not clear what chemical compounds can be used as hybridization probes to isolate said sequence of subparagraph a), and it is not even clear under what conditions the claimed chemical compounds must perform the function of hybridization to isolate the recited sequence, it is maintained that the metes and bounds of the claimed subject matter are indefinite.

In response to the rejection of claims 1-3 and 22 under §102(b), appellant states that the claimed invention is denied the benefit of the filing date of the prior applications as the prior applications do not contain an adequate written description. This statement is in error. The benefit of the filing date of parent case 07/267,577, has been denied because the parent application fails to teach how to use the 4-1BB cDNA sequence. The parent application meets neither the requirements of § 101 or § 112, first paragraph. A copy of the disclosure of parent application 07/267,577 is provided for the Board's convenience.

Following the Utility Guidelines published in 1995, when the '577 application was filed the cDNA 4-1BB clearly did not have a well-established utility. The '577 application asserts that the 4-1BB cDNA "may be used to grow the lymphokine 4-1BB" (page 19, line 14), and that "L2G25B and 4-1BB cDNA may be used as probes to isolate human lymphokines homologous to these type clones". The asserted utility of the cDNA is therefore as an intermediate in a process of making a lymphokine, or as an intermediate in a process

of isolating another cDNA. Since it is well established that a compound lacks patentable utility when its sole disclosed use is as an intermediate in making a final product of unknown utility, the analysis turns to the '577 application's disclosure of utility for the final products. The application discloses no use for the human clones isolated by using the instant cDNA. Therefore the issue of utility turns upon the use of the product encoded by the cDNA. The specification classifies the encoded product as a lymphokine, discloses the structure of the polypeptide, and provides information regarding conditions where the 4-1BB gene is expressed in T cells and splenocytes. The specification speculates that "L2G25B and 4-1BB might represent the novel soluble mediators of Prystowsky et al which affect macrophage activities" (page 14, lines 27-28, and page 18, lines 35-36). However, this statement is immediately followed by the statement "Correlation of these T cell molecules with functional activities is important" (page 14, lines 31-32). Since the specification provides no correlation between the T cell molecule 4-1BB and a functional activity, the '557 application fails to identify a specific utility for the invention. Merely designating a polypeptide as a lymphokine does not identify a specific utility for the product, since lymphokines are a broad class of proteins whose members demonstrate a plethora of different, unpredictable biological activities. The fact pattern is remarkably similar to that of In re Joly and Warnant (153 USPQ 45) and In re Kirk and Petrow (153 USPQ 49). Designation of a protein

as a lymphokine provides no more useful information than the designation of a novel chemical compound as a steroid. Description of the structure of the 4-1BB product provides no more useful information than the determination of the structural formula of a novel steroid compound. Since the '577 application does not identify a specific utility for the disclosed cDNA or the 4-1BB product encoded by the cDNA, the '577 application is seen as failing to meet the requirements of § 101, and also as failing to meet the requirements of § 112, first paragraph in failing to adequately teach how to use the disclosed product. If applicant is denied the benefit of the '577 application, Kwon et al becomes available as prior art under § 102(b). Therefore Kwon et al anticipates the claimed invention.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800

Mary E. Mosher, Ph.D.
Primary Examiner
July 15, 1996